



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-N-2671]

Drug Supply Chain Security Act Implementation and Readiness Efforts for 2023; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following virtual public meeting entitled “Drug Supply Chain Security Act Implementation and Readiness Efforts for 2023” to allow supply chain stakeholders an opportunity to share their perspectives. The topics to be discussed are stakeholder experiences with implementation and overall readiness regarding implementation of enhanced drug distribution security requirements that will go into effect on November 27, 2023, standards for the interoperable data exchange of product tracing information, requests for product tracing information or verification from FDA for the purpose of investigating suspect or illegitimate products or for recalls, steps taken to build capacity for package-level tracing, pharmaceutical distribution supply chain best practices, and, in general, the impact that the Drug Supply Chain Security Act (DSCSA) requirements would have on public health, including patient safety and access to prescription drugs, and on stakeholders, in terms of costs, benefits, and regulatory burden.

DATES: The public meeting will be held on December 7 and 8, 2022, from 10 a.m. to 3 p.m. eastern time and will take place virtually. Either electronic or written comments on this public meeting must be submitted by February 6, 2023. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public meeting will be held virtually and hosted by FDA.

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. eastern time at the end of February 6, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2022-N-2671 for “Drug Supply Chain Security Act Implementation and Readiness Efforts for 2023; Public Meeting; Request for Comments.” Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Kristle Green, Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-796-3130, CDERODSIRPublicMeetings@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On November 27, 2013, the DSCSA (title II, Pub. L. 113-54) was signed into law. The DSCSA outlines critical steps to achieve electronic, interoperable tracing at the package level by 2023 to identify and trace certain prescription drugs as they are distributed within the United States. DSCSA requirements enhance FDA’s ability to protect U.S. consumers from exposure to drugs that may be counterfeit, diverted, stolen, intentionally adulterated, or otherwise harmful by improving the detection and removal of potentially dangerous drugs from the drug supply chain.

Section 582(g)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360eee-1(g)(1)) imposed requirements for enhanced drug distribution security that go into effect on November 27, 2023. Section 582(i) of the FD&C Act directs FDA to hold public meetings to enhance the safety and security of the pharmaceutical distribution supply chain and provide opportunities for comment from members of the pharmaceutical distribution supply chain and other interested stakeholders. Since enactment of the law, FDA has held multiple public meetings that address specific topics as they relate to implementation of DSCSA requirements. As the capabilities of the pharmaceutical distribution supply chain have progressed and matured, this public meeting will be used to gather stakeholder perspectives on DSCSA implementation.

II. Topics for Discussion at the Public Meeting

- Stakeholder experiences with implementation and overall readiness regarding implementation of enhanced drug distribution security requirements that will go into effect on November 27, 2023.
- DSCSA standards for the interoperable data exchange of product tracing information for enhanced product tracing and verification.
- FDA requests to trading partners for product tracing information, verification for the purpose of investigations of suspect or illegitimate products, or recalls to support enhanced drug distribution requirements under section 582(g) of the FD&C Act.
- Steps taken by the pharmaceutical distribution supply chain to build capacity for package-level tracing, including the ability of the healthcare system to maintain patient access to medicines, scalability of DSCSA requirements, and best practices.
- Technical capabilities and legal authorities, if any, needed to establish interoperable, electronic product tracing at the package level.
- General impact that the DSCSA requirements would have on public health, including patient safety and access to prescription drugs, and on stakeholders, in terms of costs, benefits, and regulatory burden.

If other topics are identified as appropriate, FDA will post these on the designated public meeting web page prior to the meeting.

III. Participating in the Public Meeting

Registration: This will be a virtual public meeting and there are no fees for this meeting. FDA may limit registration once the meeting capacity is reached. Individuals who wish to attend the general session of the public meeting must register by December 2, 2022, and provide the following information on the public meeting registration page: Your name, organization name, stakeholder type, email address, and telephone number to FDA at <https://dscsapublicmeeting2022.eventbrite.com>. Meeting information for virtual participation will be emailed by December 5, 2022, to those that registered.

If you need special accommodations due to a disability, please contact Kristle Green (see **FOR FURTHER INFORMATION CONTACT**) no later than 7 days before the public meeting.

Breakout Sessions: Any person interested in participating in small group discussions must register by November 28, 2022, following the instructions above, and indicate your request for breakout session participation. There will be no same-day registration for breakout sessions. FDA will organize breakout sessions based on registration and interest to help ensure varied stakeholder representation, including across the pharmaceutical distribution supply chain. FDA may limit the number of participants from each organization if interest exceeds breakout session capacity.

Request for Oral Presentations: Any person interested in presenting during the public meeting must register by November 28, 2022, following the instructions above, and indicate your request to present. There will be no same-day registration for oral presentations. FDA will do its best to accommodate requests for oral presentations. Individuals and organizations with common interests are encouraged to consolidate or coordinate their presentations and can submit a single request to present. Time allotted for each presentation will depend on the number of requests received and may be limited.

FDA has verified the website addresses in this document, as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

Other Issues for Consideration: FDA will provide a recording of the public meeting and materials from the meeting at <https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa-implementation-and-readiness-efforts-2023-12072022> after the public meeting.

Dated: November 2, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.